

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ROCHE DIAGNOSTICS CORPORATION,)	
)	
Plaintiff,)	
)	
vs.)	Case No. _____
)	
MESO SCALE DIAGNOSTICS, LLC.,)	
)	
Defendant.)	
)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Roche Diagnostics Corporation (“Roche Diagnostics”) as and for its complaint against Defendant Meso Scale Diagnostics, LLC. (“Meso”), alleges as follows:

NATURE OF THIS ACTION

1. Roche Diagnostics brings this action to obtain a declaration confirming that Roche does not infringe any license rights of defendant Meso in a patented diagnostics detection technology known as electrochemiluminescence (the “ECL Technology”). This action arises under 28 U.S.C. §§ 1331 and 1338, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the United States Patent Laws, 35 U.S.C. §§ 1 *et seq.*

THE PARTIES

2. Plaintiff Roche Diagnostics is a corporation organized and existing under the laws of the State of Indiana with its principal place of business located at 9115 Hague Road, Indianapolis, Indiana 46256. Roche Diagnostics is an indirect subsidiary of Roche Holding AG, a global healthcare organization that operates worldwide under two divisions: Pharmaceuticals and Diagnostics. (As used in this Complaint, “Roche” will refer to those companies within the Roche Holding AG organization through which it conducts its Diagnostics business, including

Roche Diagnostics.) Roche conducts substantial business in the United States through Roche Diagnostics.

3. Roche Diagnostics is an affiliate of BioVeris Corporation (“BioVeris”). Both Roche Diagnostics and BioVeris are ultimately 100% owned by Roche Holding AG. BioVeris owns or exclusively licenses the rights to the patents to the ECL Technology. A list of patents relating to the ECL Technology owned by BioVeris, or to which BioVeris has exclusively licensed rights, (“BioVeris Patents”) is attached hereto as Exhibit 1. Copies of the BioVeris Patents issued in the United States are attached as Exhibit 2.¹ Roche Diagnostics markets and sells diagnostics products in the United States using the ECL Technology consistent with licenses granted to it by BioVeris in 2003 and 2007.

4. Meso is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business located at 1601 Research Boulevard, Rockville, Maryland 20850. Pursuant to a 1995 license agreement (the “1995 Meso Research License Agreement”), as amended, Meso has an exclusive license from BioVeris to use the ECL Technology, including the BioVeris Patents, in conjunction with certain other research-related technologies.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction in this case under 28 U.S.C. §§ 1331 and 1338, because this is a civil action arising under the patent laws of the United States. This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the plaintiff and

¹ Roche Diagnostics does not challenge the validity of any of the patents or patent rights owned by or exclusively licensed to BioVeris. Nor does Roche Diagnostics dispute that some of its products are covered by certain of the BioVeris Patents. Through this action, Roche Diagnostics simply seeks confirmation that it has the right to practice the ECL Technology with respect to the products it now sells pursuant to its licenses and that its practice of the ECL Technology does not violate in any way Meso’s rights under the 1995 Meso Research License Agreement, as amended. Because the BioVeris Patents themselves are not disputed, and because BioVeris and Roche Diagnostics are under common ownership and control, and in all relevant respects are aligned in interest, BioVeris need not be joined as a party in this suit.

defendant are citizens of different States and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

6. There is an actual and justiciable controversy between Roche Diagnostics and Meso in that Meso has asserted in correspondence and in other communications that Roche's use of the ECL Technology infringes Meso's exclusive license rights under the BioVeris Patents and has threatened suit on that basis. Roche has not and does not infringe the BioVeris Patents in violation of Meso's limited license rights in the ECL Technology.

7. A judicial declaration confirming that Roche's practice of the ECL Technology under the licenses granted to it does not infringe Meso's license rights under the BioVeris Patents issued in the United States is necessary and appropriate in order to resolve this controversy. Therefore, pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Roche Diagnostics is entitled to a judgment from this Court determining the scope of Meso's limited license rights and declaring that Roche Diagnostics does not infringe any of the license rights of Meso in the ECL Technology under the BioVeris Patents issued in the United States.

8. Meso is subject to personal jurisdiction in this judicial district because Meso is incorporated in Delaware pursuant to the Delaware Limited Liability Company Act, Del. Code tit. 6, § 18-101 *et seq.*

9. Venue properly lies in this district pursuant to 28 U.S.C. §§ 1391(b)(1) and (c)(2), and 1400(b).

BACKGROUND ALLEGATIONS

Roche's Acquisition and Development of the ECL Technology

10. The ECL Technology is the detection technology used by Roche Diagnostics in its line of immunoassay analyzers marketed and sold under the COBAS® brand name. Roche's immunoassays are diagnostic tests used to detect, monitor, and guide the treatment of disease and other conditions in human patients. ECL uses electricity, chemistry and light to detect and measure the presence of specific molecules in a test sample, for example molecules of a virus in a sample of blood or other bodily fluid.

11. All of Roche Diagnostics' COBAS® instruments employing the ECL Technology utilize a detection component called a "flow cell" in which the ECL reaction takes place. The flow cell is reusable, contains one permanently installed electrode, and conducts one test at a time. All of Roche Diagnostics' products sold in the United States that employ the ECL Technology are FDA-approved for use in diagnostic testing of humans.

12. Roche Diagnostics' development and commercialization of the ECL Technology dates back to 1992, when Boehringer Mannheim GmbH ("BMG"), a German company that a Roche affiliate subsequently acquired, obtained an exclusive license to the ECL Technology, including the patents described herein as the BioVeris Patents, for use in the market fields of hospitals, blood banks and clinical reference laboratories. BMG obtained that license pursuant to a License and Technology Development Agreement ("1992 BMG License") from a company called IGEN International, Inc. ("IGEN"). IGEN had acquired the ECL Technology, including the patents describing the ECL Technology, in the 1980s. BMG was acquired by a Roche Diagnostics affiliate in 1998.

13. Following lengthy litigation over various aspects of the 1992 BMG License, IGEN and an affiliate of Roche Diagnostics in 2003 entered into an additional license (the “2003 Roche License Agreement”). Pursuant to the 2003 Roche License Agreement, Roche Diagnostics’ affiliate received a non-exclusive license to, among other things, develop, manufacture, and sell products using the ECL Technology, including the BioVeris Patents, in a defined field (the “2003 Roche Field”) that included all human testing for detection of disease, patient treatment and monitoring purposes, without limitation as to the type of customer. The 2003 Roche Field specifically excluded use of ECL Technology in connection with the multi-array assays, disposable electrodes and related research technologies that were subject to Meso’s limited license. Roche Diagnostics received a sublicense under the 2003 Roche License Agreement. In connection with the transaction by which Roche Diagnostics’ affiliate obtained the license under the 2003 Roche License Agreement, IGEN spun off much of its business, including the BioVeris Patents, to a new company, BioVeris.

14. Meso was not a party to the 2003 Roche License Agreement, and it did not grant to Roche any of the ECL rights that Roche uses in conjunction with its COBAS® products. Meso did, however, expressly consent to the entire 2003 Roche License Agreement, including, among other things, to IGEN’s representations therein that IGEN held the rights being licensed to Roche and to Roche’s ability through the licenses granted to practice ECL Technology within the 2003 Roche Field.

15. In 2007, an affiliate of Roche Diagnostics acquired BioVeris, along with its patents and other rights in the ECL Technology, as well as BioVeris’ M-Series line of diagnostic instruments, which used some of the same relevant technology components as the Roche ECL-based COBAS® instruments. Thereafter, BioVeris granted a second, further license to Roche

(the “2007 Roche License Agreement”) to use the ECL Technology, including the BioVeris Patents, in market fields outside the 2003 Roche Field. This second license again specifically excluded any rights previously granted to third parties by IGEN or BioVeris, including those of Meso. Roche has never marketed or sold products utilizing the ECL Technology in any way connected to Meso’s multi-array assays, disposable electrodes and related research technologies.

16. Over the course of the more than 20 years that Roche has spent developing and marketing products using the ECL Technology, it has built its diagnostics business into a world leader. Its diagnostics products, including those using the ECL Technology, are sold through Roche Diagnostics in every state in the United States.

Meso’s 1995 Research License Agreement and Products

17. Meso also is a licensee under IGEN’s (now BioVeris) ECL Technology. Meso was formed as a joint venture in 1995 between IGEN and Meso affiliate Meso Scale Technologies, LLC. (“MST”). MST had been working with certain research technologies that allowed multiple tests to be performed in a single reading using a multi-well tray (so-called “multi-array” technology) and with disposable electrodes. The joint venture was formed to explore potential combinations of the ECL Technology with MST’s multi-array and disposable electrode technologies.

18. In furtherance of the joint venture, IGEN licensed Meso to use certain rights, including the BioVeris Patents, to pursue ECL in connection with defined “Research Technologies” and a “Research Program,” both of which were defined according to and focused upon the above-referenced multi-array and disposable electrode technologies. The license was memorialized in the 1995 Meso Research License Agreement. The 1995 Meso Research License Agreement was subsequently amended in 2001 and 2004.

19. Meso manufactures and/or sells ECL-based analyzers, multi-well trays, and reagents for use in scientific research, including in connection with early-stage drug discovery. All of Meso's commercially-sold products utilize multi-array, disposable electrode technologies. Meso does not offer any FDA-approved tests.

20. Meso's multi-array or disposable electrode technologies are different from Roche Diagnostics' single-cell, permanent electrode technology and result in much different instruments, for use in much different markets than those of Roche Diagnostics. Roche Diagnostics cannot and does not use any multi-array or disposable electrode technologies in its ECL-based COBAS® instruments.

The 2010 Delaware Litigation

21. Over the years, Meso has attempted to use its limited rights under the 1995 Meso Research License to threaten Roche and extract payment by claiming that Roche has somehow been violating Meso's limited rights.

22. In 2010, Meso sued Roche Diagnostics and several of its affiliates in the Delaware Court of Chancery, C.A. 5589-VCP. In its complaint in that Delaware suit, Meso alleged that Roche was selling products using the ECL Technology outside the 2003 Roche Field and in breach of the 2003 Roche License Agreement.

23. Among other things, Meso attempted to challenge Roche's sales of its ECL-based products pursuant to the 2007 Roche License, alleging that Meso had been a grantor of rights under and party to the 2003 Roche License Agreement and thus had standing to enforce the field limitations in that agreement. Meso further claimed that it could enforce the field limitations because of a "Consent by Meso Scale Diagnostics, LLC. and Meso Scale Technologies, LLC."

(the “Meso Consent”) that Meso provided in connection with the transaction by which Roche acquired its license under the 2003 Roche License Agreement.

24. In reality, Meso had been asked to and did sign the Meso Consent because it was another licensee under the ECL Technology and had obscured the scope and nature of its rights under the 1995 Meso Research License Agreement. The purpose of the Meso Consent was to obtain Meso’s assurance that it would not and could not assert its rights under its 1995 License Agreement, as amended, to interfere with Roche’s licensed use of the ECL Technology.

25. Nevertheless, on the basis of the Meso Consent, Meso alleged in the prior Delaware litigation that it was entitled to damages for Roche’s alleged breaches due to sales outside the 2003 Roche Field, and a permanent injunction barring Roche from making future sales outside the 2003 Roche Field.

26. In its complaint and in the case it advanced over the next several years and at trial, Meso’s theory was that the 1995 Meso Research License Agreement, as amended, had given Meso undefined “broad” exclusive rights in the ECL Technology, including the BioVeris Patents, and that because of those rights IGEN could not grant any license to Roche unless Roche also obtained a license from Meso. Therefore, according to Meso, the Meso Consent also made Meso a licensor of ECL Technology rights to Roche, which gave it enforcement rights.

27. The Delaware Court of Chancery suit went to trial in February 2013. After a five-day bench trial and post-trial briefing and argument, on June 25, 2014, Vice Chancellor Donald F. Parsons in a detailed 77-page decision found in favor of Roche and dismissed Meso’s claims with prejudice. *Meso Scale Diagnostics, LLC. et al. v. Roche Diagnostics GmbH et al.*, 2014 WL 2919333 (Del. Ch. 2014). Vice Chancellor Parsons unequivocally rejected Meso’s claims to being a party to and having rights to enforce the 2003 Roche License Agreement. The Vice

Chancellor further rejected Meso's theory, which had been based upon its asserted "broad rights" under its 1995 Meso Research License Agreement, as amended, that it was a licensor of the ECL Technology.

28. On June 18, 2015, the Delaware Supreme Court summarily affirmed the judgment of the Court of Chancery. *Meso Scale Diagnostics, LLC., et al. v. Roche Diagnostics GmbH, et al.*, No. 389, 2014, 116 A.3d 1244 (Table), 2015 WL 3824809 (June 18, 2015).

Meso Assertions of Infringement by Roche Diagnostics and Continued Litigation Threats

29. Following the Delaware Supreme Court's affirmance of the Court of Chancery judgment, Meso through its litigation counsel notified Roche that, in its view, the Delaware litigation had still not resolved all of the parties' disputes. Meso and its counsel have asserted in correspondence and other communications that Meso retains the right to litigate against Roche and threatened litigation claiming that the activities of Roche infringe Meso's rights under the 1995 Meso Research License Agreement.

COUNT I

Declaratory Judgment of Non-Infringement of Meso's License Rights

30. Roche Diagnostics incorporates and realleges the preceding paragraphs as if set forth fully herein.

31. Meso claims that it is the exclusive licensee of "broad rights" under the patented ECL Technology, including the BioVeris Patents.

32. Meso has asserted that Roche Diagnostics' products infringe Meso's exclusive license rights under the BioVeris Patents.

33. Contrary to Meso's assertions, Roche Diagnostics does not violate any of Meso's limited exclusive license rights in the ECL Technology under the BioVeris Patents and thus has not infringed and does not infringe the BioVeris Patents.

34. In addition to Roche's actual non-infringement of any rights of Meso, any suit by Meso, such as it has threatened to initiate, alleging infringement by Roche Diagnostics of Meso's limited exclusive license rights would be barred in whole or in part by the doctrines of claim and issue preclusion. As alleged in foregoing paragraphs, Meso previously made the same allegations with respect to its rights and infringement by Roche in the Delaware Litigation. The Delaware courts, in the final judgment and in factual findings leading to that judgment, rejected Meso's position. Those claims and issues cannot be re-litigated by Meso now.

35. Moreover, any claims of infringement by Meso now would be barred, in whole or in part, by the applicable statute of limitations and under the doctrines of laches, estoppel, and waiver. Meso by its own admission has known since no later than 2007 of the scope of Roche's sales and other activities relating to its ECL products. Yet Meso has delayed in taking legal action to assert its purported rights. Instead, Meso in 2010 sued under a baseless contractual theory which, after five years of litigation, was unequivocally rejected by the Delaware courts.

36. Nonetheless, Meso persists in making unfounded accusations of infringement by Roche and threatening to initiate new litigation.

37. An actual and justiciable controversy therefore exists between Roche Diagnostics and Meso regarding the alleged infringement of Meso's exclusive license rights under the BioVeris Patents issued in the United States.

38. A judicial declaration of non-infringement is necessary and appropriate in order to resolve this controversy.

39. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 and 2202, Roche Diagnostics is entitled to judgment from this Court that Roche Diagnostics does not violate any of Meso's limited exclusive license rights in the ECL Technology under any of the BioVeris Patents issued in the United States.

PRAYER FOR RELIEF

WHEREFORE, Roche Diagnostics respectfully requests that this Court enter judgment in its favor as follows:

- a. Declaring that Roche Diagnostics has not violated and does not violate any of Meso's limited exclusive license rights in the ECL Technology under the BioVeris Patents issued in the United States;
- b. Declaring that Roche Diagnostics has not infringed and does not infringe the BioVeris Patents issued in the United States, as licensed to Meso;
- c. Declaring that this case is exceptional pursuant to 35 U.S.C. § 285, and awarding Roche Diagnostics its reasonable attorneys' fees and costs;
- d. Awarding Roche Diagnostics its costs, disbursements, and other expenses to the fullest extent permitted by law; and
- e. Awarding Roche Diagnostics such other and further relief as the Court deems just and proper.

/s/ Joel Friedlander

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